# Exciting FDA Events at SNM Annual Meeting

Continuing an exciting and highly beneficial tradition, Food and Drug Administration (FDA) staff members will host a continuing education session on FDA issues at the 2006 SNM Annual Meeting in San Diego, CA. Presenters and topics tentatively scheduled include George Mills, MD, MBA, who will speak on Imaging Biomarkers and Imaging Standardization for Clinical Trials; Alex Gorovets, MD, who is scheduled to discuss the Development of Imaging Product: Regulatory Perspective; Kaye Kang, who will discuss Highlights of Standard Meetings with the Medical Imaging Division; Tiffany Brown, who will speak on Navigating the Process of Imaging Submissions; Florence Moore, who will present the Comparison of BLA and NDA Regulatory Requirements for Biotechnology Products; and Tushar Kokate, who is scheduled to speak on Exploratory IND Studies in Humans: Preclinical Requirements. The exact time and date of the session had not been announced as Newline went to press.

The FDA staff will also host a separate business meeting on the morning of June 5 (Monday) tentatively featuring discussions from Ravindra Kasliwal, PhD, on Chemistry, Manufacturing and Controls for PET Drugs and Thuy Nguyen on the Administrative Steps to Submitting a PET-FDG NDA. A discussion with FDA staff about the Radioactive Drug Research Committee process will follow these presentations.

### NRC NARM Regulations

The Nuclear Regulatory Commission (NRC) naturally occurring and accelerator-produced nuclear materials (NARM) regulations required by Section 651(e) of the Energy Policy Act of 2005 should be available for public comment by the time you receive this issue of *The Journal of Nuclear Medicine*, according to the NRC timetable. SNM is interested in how the NRC proposes to regulate cyclotron products and whether the commission will attempt to assume authority over everything activated by the production process, including the accelerators themselves.

### Basic Nuclear Medicine Research Funding

SNM staff and consultants are continuing to work toward finding a permanent home for basic scientific research pertaining to nuclear medicine within the Department of Energy (DOE), National Institutes of Health, or some another agency. Hill meetings between SNM staff, consultants, and Senate and House appropriators for Health and Human Services and Energy and Water issues are held on a regular basis, and the various appropriations subcommittees are currently holding preliminary hearings to discuss the fiscal year 2007 budget, so we are hopeful that the research appropriations cut from the DOE budget will find a home in another agency.

**Hugh Cannon**
**SNM Director of Public Affairs**

### RadCARE Bill (S 2322)

On February 17, the RadCARE bill (S 2322)—the Senate version of the Consumers Assurance of Radiologic Excellence bill (HR 1426)—was introduced in the 109th Congress by Senator Michael B. Enzi (R-WY) and by Senator Edward M. Kennedy (D-MA), chair and ranking minority member of the committee of jurisdiction, the Health, Education, Labor and Pensions Committee. This is extremely good news for the nuclear medicine technology community, as the legislation on the Senate side is now far more likely to move through committee than ever before.

### CARE Bill (HR 1426)

At this writing, the CARE bill has 118 cosponsors in the House of Representatives.

### ASRT "RT in DC" Meeting

The annual "RT in DC" meeting (March 12–14) went exceptionally well with solid representation from the nuclear medicine technology community. The event featured an educational session on grassroots advocacy from DC-area lobbyists and Capitol Hill staffers, followed by a day of legislative appointments as approximately 130 radiologic and nuclear medicine technologists converged on Capitol Hill to advocate for the CARE legislation. Two senators were added to the cosponsor list for Senate bill and 5 representatives were added to the cosponsor list for the House version as a result of the American Society of Radiologic Technologists–sponsored event.